

# TECHNICAL AGREEMENT

MADE AND ENTERED INTO BY AND BETWEEN

(herein after referred to as "THE PRINCIPAL")

**AND**

**BIOMOX PHARMACEUTICALS (PTY) LTD.**

REG. NO. 93/00773/07

429 DEKGRAS ROAD

SILVERTONDALE

PRETORIA

(herein after referred to as "THE CONTRACTOR")

## **WHEREAS:**

1. The CONTRACTOR has at his disposal the facilities, expertise and infrastructure for the manufacturing and packaging of certain products.
2. The PRINCIPAL is the licensee and/or owner of certain products in South Africa as well as the owner of certain data information related to said products.
3. The PRINCIPAL is desirous of making use of the CONTRACTORS' expertise, facilities and infrastructure for the manufacture and/or packaging of its' products.
4. The PRINCIPAL and the CONTRACTOR are desirous of reducing their agreement in writing.

## **NOW THEREFORE, IT IS AGREED THAT:**

1. This agreement shall be for a period of 1 year whereafter it shall continue indefinitely subject to a termination period of 3 months written notice, such notice to be delivered by the party so wishing to terminate this agreement to the other on or before the last day of the month preceding the termination period.
2. This agreement shall commence upon signature hereof by both parties whereafter all the conditions shall become binding on both parties. Should any work be done prior to the signing of this agreement then such work shall be performed as if this agreement has been in force.
3. The CONTRACTOR shall invoice the PRINCIPAL in accordance with the official purchase order details, and payment for receipt of goods shall be made strictly within 30 days from date of statement.
4. **The CONTRACTOR undertakes to:**
  - 4.1 Comply with the MBR1 specification in terms of Manufacturing Packaging and Quality Control where applicable or as specified by "the PRINCIPAL" in writing, the aforesaid being specified more fully in Annexure 1. Biomox will be responsible for the receiving and release of packing components. The procedures followed will be in accordance with Good Manufacturing Procedures as stipulated in Biomox Standard Operating Procedures.
  - 4.2 Where independent laboratory release testing is required, the CONTRACTOR undertakes to provide such independent laboratory with representative samples for release purposes. However, the CONTRACTOR shall not accept any responsibility for the validity of results so

obtained, and the PRINCIPAL indemnifies the CONTRACTOR for any loss or liability that may arise as a result of work performed by and results obtained from such independent laboratory. The cost will be charges to the PRINCIPAL.

- 4.3 The CONTRACTOR undertakes to maintain standards of Good Manufacturing Practice at all times. The printed components and packaging materials shall be released by Biomox. Printed components must receive prior approval from the PRINCIPAL.
- 4.4 The CONTRACTOR will prepare master documentation for manufacturing, packing and quality control procedures in compliance with the MBR1 documentation or other relevant specifications. The master documentation will be kept as a permanent record by the PRINCIPAL but will remain the property of the CONTRACTOR, unless purchased by the PRINCIPAL at a price agreed dependent of time spent and preparation costs.
- 4.5 The CONTRACTOR accepts the confidentiality of all information related to the products. For purposes of this clause the following definitions shall apply.
- a. "Information" means information and data supplied by the PRINCIPAL or generated by the CONTRACTOR pursuant to this agreement whether written, graphic or oral, including operating instructions, designs, material and production specifications, formulae, drawings, blueprints and other technical and statistical and commercial information, together with any samples or specimens thereof.

**5. The CONTRACTOR hereby agrees and undertakes:**

- 5.1 To communicate the Information solely to those of its' employees who reasonably require the same for the purposes hereof and who are bound to the CONTRACTOR by like obligations as to confidentiality.
- 5.2 Not otherwise to disclose the Information to any person, firm or company, without the prior written consent of the PRINCIPAL.
- 5.3 Upon conclusion of the purposed aforesaid or sooner at the PRINCIPAL's request, to return all the Information to the PRINCIPAL, together with all copies thereof.
- 5.4 Where the PRINCIPAL supplies material to be used in the manufacture or packaging of the product, the CONTRACTOR undertakes to store such materials. The CONTRACTOR undertakes to maintain adequate insurance cover over such material and will take any such precaution as can reasonably be expected of him to safeguard the PRINCIPAL against losses. Where raw materials or packaging materials are supplied by the PRINCIPAL, the following maximum wastage allowances will be applicable: 5%
- 5.5 Where the CONTRACTOR is responsible for the procurement of materials for the purpose of manufacture or packaging he shall do so in accordance with the purchase order supplied by the PRINCIPAL.
- 5.6 The CONTRACTOR shall not be liable for any claims of whatever nature that may arise from the distribution, usage or sale of the products except where such claims may arise as a result of the negligence of the CONTRACTOR in the manufacturing and/or packaging process, such negligence to be proven beyond any doubt beforehand. The PRINCIPAL specifically indemnifies the CONTRACTOR against any claim that may arise due to inherent formulation deficiencies or incorrect material and procedural specifications.

- 5.7 **The PRINCIPAL undertakes to:**
- 5.8 Provide the CONTRACTOR with the latest updated information with regard to the MBR1 document or other relevant specifications.
- 5.9 Where the PRINCIPAL shall be responsible for providing raw materials and/or packing components he shall ensure that such materials and/or packing components conform to the specifications as per the MBR1 document or other relevant specifications (as well as acceptable Certificate of Analysis of any and/or all raw materials used), and the CONTRACTOR shall accept no responsibility for any losses or claims which may arise as a result of such non-conformity.
- 5.10 The PRINCIPAL shall provide the CONTRACTOR monthly with an updated sales forecast for the following 3-month period.
- 5.11 The PRINCIPAL shall monitor all products and shall ensure that all expired products are destroyed at his own expense.
- 5.12 The PRINCIPAL shall confirm stability of all pharmaceutical products and shall keep the CONTRACTOR updated as regards to any changes related to product specification.
- 5.13 The PRINCIPAL shall have access to the CONTRACTOR's premises at any reasonable time upon giving the CONTRACTOR notice of his intention to inspect the premises. The PRINCIPAL shall notify the CONTRACTOR of the identity of the persons so to inspect the said premises and shall ensure that the said persons shall abide by the CONTRACTOR's rules and regulations with special regards to those pertaining to the CONTRACTORS' obligations in terms of secrecy and confidentiality.
- 5.14 The PRINCIPAL undertakes to pay the CONTRACTOR 30 days from statement unless agreed otherwise in writing at the prices set out in Annexure A.
- 5.15 The PRINCIPAL undertakes to conform to the Medicines and Related Substances Act 101 of 1968 as amended, or any other applicable act or new act or regulation governing medicine or other relevant substances.
- 6 "PRODUCTS" shall mean the finished products formulated and/or from MATERIALS, in accordance with the process and work described in the Standard Operating Procedures and/or specified formula.
- 7 "MATERIALS" shall mean the active ingredient, raw materials, surfactants, solvents, bottles, caps, cartons and any other raw materials necessary to formulate and/or pack PRODUCTS.
- 8 **SUPPLY OF MATERIALS AND PACKAGING MATERIALS:**
- 8.1 Biomox shall acquire all MATERIALS needed in the manufacturing of the PRODUCT unless otherwise specified.
- 8.2 The PRINCIPAL shall supply the CONTRACTOR with the necessary artwork as to be applied to the packaging.
- 8.3 Each order placed by the PRINCIPAL with the CONTRACTOR for the final product shall—
- a. Be in writing.

- b. Specify those products required to be manufactured, the quantities thereof and the date or dates upon which delivery thereof is required, by means of the official request/order form. (See Addendum).
- c. Be given so as to reach the CONTRACTOR at least thirty (30) days before the earliest delivery date stipulated therein, or such earlier date as may be agreed to in writing between the Parties.

## **10. QUALITY ASSURANCE**

- 10.1 The CONTRACTOR shall take and analyse MATERIAL samples for quality and positive identification purposes as detailed in the Standard Operating Procedures, (where applicable) and shall also take, analyse and retain PRODUCT samples (where applicable). This is subject to testing methods being available for the MATERIAL, the costs of such testing will be given through to the PRINCIPAL. The CONTRACTOR shall provide the PRINCIPAL with these samples on request. For disposal of the samples refer to Clause 6.4.

## **10.2 RISKS**

The PRINCIPAL will in no way act in any manner that is or could be seen as a contravention of any act/regulation regulating medicine or related products and hereby holds the CONTRACTOR harmless from any action relating thereto and/or the actual working or possible side-effects of the actual formula.

## **11 PRODUCTION CONTROL**

### **11.1 Batch numbering system**

The contract acceptor's system will be used. The CONTRACTOR will provide the PRINCIPAL with an explanation/key to enable the Batch Numbering System to be decoded when required to do so.

- 11.2 Reworking and related situations will be handled according to Good Manufacturing Procedures.
- 11.3 If there is a significant quantity of bulk or packed stock to be reworked, the PRINCIPAL must obtain the written consent of the CONTRACTOR.
- 11.4 All rework material deemed unfit for use from the manufacturing process must be destroyed by the CONTRACTOR and securely and safely disposed of. The cost of such rework and/or disposal procedure will be for the PRINCIPAL.

## **12 BATCH YIELD**

### **12.1 Product**

An acceptable product yield will be agreed between the PRINCIPAL and the CONTRACTOR.

## **13 This contract will terminate upon:**

- 13.1 The one party giving the other party 3 month's written notice of his intention to cancel this agreement provided:
- 13.2 Such notice be given in writing on or before the last calendar day of the month preceding the month in which the notice period commences.

- 13.3 Any party remaining in breach after receiving 21 days' written notice to rectify such breach provided that such written notice is delivered either by hand or by registered mail to the defaulting party's registered address.
- 13.4 Should any party commit an act of insolvency, enter into a compromise with its' creditors or be placed under judicial management. For such purposes the PRINCIPAL recognizes that the CONTRACTOR holds an hypothec over all products manufactured and/or packaged until all amounts due and payable by the PRINCIPAL to the CONTRACTOR have been settled.
- 13.5 No indulgence of any nature whatsoever by one party shall be construed in such a way so as to diminish, inhibit or infringe upon the rights and obligations of the other party.
- 13.6 No change, deletion, addition, cancellation, session, delegation or any other legal action in relation to this agreement shall be of any effect whatsoever unless reduced in writing and signed by both parties.
- 13.7 For the purposes of any notice in terms hereof and for the service of any process, the CONTRACTOR chooses the following address as its domicilium citandi et executandi namely:

**429 Dekgras Road  
Silvertondale  
Pretoria**

Likewise the PRINCIPAL chooses as his domicilium citandi et executandi:

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## **ANNEXURE 1**

### **SPECIFIC PROCEDURES FOR MANUFACTURING AND PACKAGING**

1. Raw materials will be tested in compliance with MBR1 or other relevant specifications with regard to:
  - a. Supplier (where applicable)
  - b. Specifications
  - c. Testing procedures applied
2. Masters for specification manufacturing. Quality Control and testing procedures will be kept as permanent record and followed through with every batch manufactured.
3. Line openings and in-process checks shall be executed under supervision of a pharmacist.
4. Retention samples will be kept from each batch of product manufactured for a period of one year after the expiry date of the product.

**THIS AGREEMENT SHALL BE BINDING ON BOTH PARTIES AND MAY ONLY BE CANCELLED BY MUTUAL AGREEMENT IN WRITING**

**FOR AND ON BEHALF OF**

**BIOMOX PHARMACEUTICALS (PTY) LTD.  
REG. NO. 93/00773/07  
429 DEKGRAS ROAD  
SILVERTONDALE  
PRETORIA**

Signature.....

Witness (1).....

Witness (2).....

Signed at.....Month.....Day.....Year.....

**FOR AND ON BEHALF OF:**

Signature.....

Witness (1).....

Witness (2).....

Signed at.....Month.....Day.....Year.....